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Commissioner for Patents
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David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
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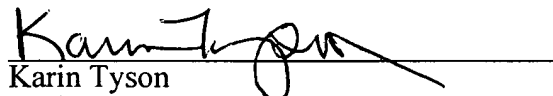
Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,808,665, which issued September 15, 1998, was filed on September 11, 2000, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, VINCITTM System, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within sixty days after the product was approved. The application for patent term extension raises the issue of whether the application was subject to a regulatory review period under 35 U.S.C. § 156(g) because the approval for commercial marketing or use is said to have been under § 510(k) of the Federal Food, Drug and Cosmetic Act, which is not the same as an approval under § 515 of said Act. A regulatory review period under section 510(k) of the Federal Food, Drug and Cosmetic Act is not a regulatory review period which gives rise to eligibility for patent term extension under 35 U.S.C. 156. *In re Nitinol Medical Technologies Inc.*, 17 USPQ2d 1492, 1492-1493 (Comm'r Pat. & Tm. 1990). *See also Baxter Diagnostics v. AVL Scientific Corp.*, 798 F. Supp. 612, 619-620; 25 USPQ2d 1428, 1434 (CD CA 1992) (Congress intended only Class III medical devices to be eligible for patent term extension).

Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.


Karin Tyson

Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

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